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24280 7590 08/01/2008 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER HOLT, ANDRIAE M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

This Office Action is in response to the amendment filed April 14, 2008. Claims 35-42 and 44-55 are pending in the application. Claim 43 has been cancelled. Claims 44-55 are newly added.

Status of the Claims

The rejection of claim 43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,326,020 has been overcome by the cancellation of claim 43. The rejection of claim 43 **is moot**.

Claim Rejections - 35 USC § 102

The examiner confirms the rejection of claims 35-43 was a rejection under 35 U.S.C. 102 (e), not 35 U.S.C. 102(b).

The rejection of claims 35-42 under 35 U.S.C. 102(e) as being anticipated by Kohane et al. (US 6,326,020) **is maintained**.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Kohane et al. (US 6,326,020).

Applicant claims a pharmaceutical composition for suppressing electrical activity in an electrically excitable tissue comprising a site 1 sodium channel blocker, a local anesthetic and a glucocorticoid receptor agonist. The electrically excitable tissue includes brain, heart and uterine tissue.

Kohane et al. disclose combinations of naturally occurring site 1 sodium channel blockers (claims 35, 39 and 43, site 1 sodium channel blockers, instant invention), such as tetrodotoxin (TTX) (claim 39, tetrodotoxin, instant invention), saxitoxin, decarbamoyl saxitoxin and neosaxitoxin with other agents to give long duration block with improved features, including safety and specificity (col. 2, lines 30-35). Kohane et al. disclose in one embodiment, duration of block is greatly prolonged by combining a toxin with a local anesthetic and glucocorticoid (col. 2, lines 36-38)(claims 35, 39-41 and 43, site 1, sodium channel blocker, tetrodotoxin, local anesthetic and glucocorticoid, instant invention). Kohane et al. further disclose that bupivacaine is the preferred local anesthetic (col. 7, lines 21-22) (claim 40, bupivacaine, instant invention). Kohane et al. disclose corticosteroids that are useful to prolong in vivo nerve blockade include glucocorticoids such as dexamethasone (col. 7, lines 1-2) (claims 40 and 42, dexamethasone, instant invention). Kohane et al. further disclose in example 5, col. 20, lines 26-52, the combination of tetrodotoxin with bupivacaine and epinephrine with 0.2% dexamethasone (claims 35 and 39-43, tetrodotoxin, bupivacaine and dexamethasone in combination, instant invention). Kohane et al. disclose the combination of tetrodotoxin

with bupivacaine provides blockade with durations of about 10 hours and the addition of dexamethasone can produce blockade in excess of 30 hours (col. 20, lines 38-52). A combination of tetrodotoxin, bupivacaine and dexamethasone is taught at col. 4, lines 20-25. The claimed "tissue" is not part of the claimed composition; it is intended use.

Response to Arguments

Applicant's arguments filed April 14, 2004 have been fully considered but they are not persuasive. Applicant has submitted a Declaration under 37 C.F.R. 1.132 by Dr. Daniel S. Kohane establishing that the claimed invention is not invented by another.

In response to applicant's argument and declaration, MPEP 2136.04 states, "Another" means other than applicants, *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). Dr. Kohane declares in statement number 4, Charles B. Berde, Gary Strichartz and Robert S. Langer are the co-inventors on the '020 patent and in statement number 5, Berde and Strichartz are not inventors of the claimed invention of the '032 application. Therefore, as evidenced by Dr. Kohane's declaration not all inventors are the same, a different inventive entity. As stated by the House and Senate reports on the bills enacting section 35 U.S.C. 102(e) as part of the 1952 Patent Act, this subsection of 102 codifies the Milburn rule of *Milburn v. Davis-Bournonville*, 270 U.S. 390 (1926). The Milburn rule authorized the use of a U.S. patent containing a disclosure of the invention as a reference against a later filed application as of the U.S.

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patent filing date. The existence of an earlier filed U.S. application containing the subject matter claimed in the application being examined indicates that applicant was not the first inventor. Therefore, a U.S. patent, a U.S. patent application publication or international application publication, by a different inventive entity, whether or not the application shares some inventors in common with the patent, is *prima facie* evidence that the invention was made "by another" as set forth in 35 U.S.C. 102(e).

The claims remain rejected.

The rejection of claims 35-42 under 35 U.S.C. 103(a) as being unpatentable over the Kohane et al. (US 6,326,020) in view of Levin (US 2002/00101094) **is maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Kohane et al. (US 6,326,020) in view of Levin (US 2002/00101094).

Applicant's Invention

Applicant claims a pharmaceutical composition for suppressing electrical activity in an electrically excitable tissue comprising a site 1 sodium channel blocker, a local anesthetic and a glucocorticoid receptor agonist. The electrically excitable tissue includes brain, heart and uterine tissue.

Determination of the scope of the content of the prior art

(MPEP 2141.01)

The teachings of Kohane et al. are incorporated herein by reference and are therefore applied in the instant rejection as discussed above. Kohane et al. also teach that bupivacaine is a particularly long acting and potent local anesthetic when incorporated into a polymer. Kohane et al. teach that its other advantages include sufficient sensory anesthesia without significant motor blockage, lower toxicity and wide availability (col. 7, lines 24-28).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Kohane et al. do not explicitly teach that the electrically excitable tissue is brain tissue. It is for this reason Levin is joined.

Levin teaches pharmaceutical compositions useful for inhibiting a cerebral neurovascular disorder or a muscular headache in a patient (page 6, paragraph 64). Levin teaches that cerebral neurovascular disorders may be selected from the group consisting of cerebrovascular spasm, seizure, and a neurovascular headache (page 5, paragraph 59)(claim 36, brain tissue, instant invention). Levin teaches the long acting anesthetic pharmaceutical composition comprises a pharmaceutically acceptable carrier and at least one local anesthetic ingredient selected from the group consisting of a long-acting local anesthetic, a persistent local anesthetic and a sustained release formulation of a local anesthetic (page 6, paragraph 60). Levin further teaches in claim 5, page 32, the local anesthetic is bupivacaine (claims 35, 40 and 43, local anesthetic, bupivacaine, instant invention). Levin teaches in an alternate embodiment the long acting local anesthetic pharmaceutical composition further comprises a pharmaceutically active agent such as tetrodotoxin and a glucocorticoid compound (page 6, paragraph 61) (claims 35, 39-43, tetrodotoxin, local anesthetic and glucocorticoid receptor agonist).

Finding a prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Kohane et al. and Levin to produce a pharmaceutical composition that would be effective in treating a disorder that affects brain tissue. As taught by Kohane et al. the combination of tetrodotoxin, bupivacaine and dexamethasone produced a safe, specific, and potent composition for intercostal

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blockade for thoracic post-therapeutic neuralgia, lumbar sympathetic blockade and modality-selective blockade for epidural infusion for postoperative pain. It is known in the art that nerve tissue is electrically excitable tissue. Levin teaches that a local anesthetic composition alone or in combination with tetrodotoxin or a glucocorticoid compound is effective in treating cerebral neurovascular disorders. Thus, as the compositions safely and effectively treat disorders of electrically excitable tissues, one skilled in the art at the time of invention would have been motivated to combine the teachings.

Response to Arguments

Applicant's arguments filed April 14, 2004 have been fully considered but they are not persuasive. Applicant argues that Kohane cannot be considered as part of the basis for an obviousness rejection based on the Declaration submitted under 37 C.F.R. 1.132 by Dr. Daniel S. Kohane establishing that the claimed invention is not invented by another.

In response to applicant's argument and declaration, MPEP 2136.04 states, "Another" means other than applicants, *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). Dr. Kohane declares in statement number 4, Charles B. Berde, Gary Strichartz and Robert S. Langer are the co-inventors on the '020 patent and in statement number 5, Berde and Strichartz are not inventors of the claimed invention of

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the '032 application. Therefore, as evidenced by Dr. Kohane's declaration not all inventors are the same, a different inventive entity. As stated by the House and Senate reports on the bills enacting section 35 U.S.C. 102(e) as part of the 1952 Patent Act, this subsection of 102 codifies the Milburn rule of *Milburn v. Davis-Bournonville*, 270 U.S. 390 (1926). The Milburn rule authorized the use of a U.S. patent containing a disclosure of the invention as a reference against a later filed application as of the U.S. patent filing date. The existence of an earlier filed U.S. application containing the subject matter claimed in the application being examined indicates that applicant was not the first inventor. Therefore, a U.S. patent, a U.S. patent application publication or international application publication, by a different inventive entity, whether or not the application shares some inventors in common with the patent, is *prima facie* evidence that the invention was made "by another" as set forth in 35 U.S.C. 102(e).

The claims remain rejected.

The rejection of claims 35-42 under 35 U.S.C. 103(a) as being unpatentable over the Kohane et al. (US 6,326,020) in view of Webb et al. (US 2001/002404) **is maintained.**

Claims 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Kohane et al. (US 6,326,020) in view of Webb et al. (US 2001/002404).

Applicant's Invention

Applicant claims a pharmaceutical composition for suppressing electrical activity in an electrically excitable tissue comprising a site 1 sodium channel blocker, a local anesthetic and a glucocorticoid receptor agonist. The electrically excitable tissue includes brain, heart and uterine tissue.

Determination of the scope of the content of the prior art

(MPEP 2141.01)

The teachings of Kohane et al. are incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Kohane et al. do not teach the electrically excitable tissue being heart and uterine tissue. It is for this reason Webb is joined.

Webb et al. teach that conjugates of pharmaceutical agents and a highly lipophilic group, a C8-C26, naturally occurring unbranched carbon chain, have a different selectivity relative to the unconjugated pharmaceutical agents (page 2, paragraph 19). Webb et al. teach in one embodiment, the conjugates render the activity of these conjugates selective for colon tissue, breast tissue and central nervous system tissue (page 2, paragraph 20) (claim 36, brain tissue (nervous system), instant invention). Webb et al. teach that a method is provided for targeting a therapeutic agent to noncentral nervous system tissue to treat a noncentral nervous system condition

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(page 2, paragraph 21). Webb et al. further teach the noncentral nervous system tissue can be tissue from the cardiovascular system including heart and vascular system (claim 37, heart tissue, instant invention) and reproductive system including uterus (claim 38, uterine tissue, instant invention) (page 2, paragraph 21-page 3 paragraph 21). Webb et al. teach that the pharmaceutical agent may be any pharmacological compound or diagnostic agent (page 3, paragraph 24). Webb et al. further teach that anesthetic agents include bupivacaine (page 12, paragraph 105)(claim 40, local anesthetic, bupivacaine, instant invention). Webb et al. also teach that glucocorticoid agents include dexamethasone (page 21, paragraph 212) (claims 41-42, glucocorticoid receptor, dexamethasone).

Finding a prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Kohane et al. and Webb et al. to produce a pharmaceutical composition that would be effective in treating a disorder that affects brain, heart and uterine tissue. As taught by Kohane et al., the combination of tetrodotoxin, bupivacaine and dexamethasone produced a safe, specific, and potent composition for intercostal blockade for thoracic post-therapeutic neuralgia, lumbar sympathetic blockade and modality-selective blockade for epidural infusion for postoperative pain. Webb et al. teach that the combination of a pharmaceutical agent with a fatty acid provides a method for selectively targeting pharmaceutical agents to desired tissues. Agents

claimed in the instant invention are cited. One skilled in the art the time of invention would have been motivated to combine the teachings to produce a pharmaceutical agent that is effective, highly selective and safe in treating disorders of the heart, brain and uterus.

Response to Arguments

Applicant's arguments filed April 14, 2004 have been fully considered but they are not persuasive. Applicant argues that Kohane cannot be considered as part of the basis for an obviousness rejection based on the Declaration submitted under 37 C.F.R. 1.132 by Dr. Daniel S. Kohane establishing that the claimed invention is not invented by another.

In response to applicant's argument and declaration, MPEP 2136.04 states, "Another" means other than applicants, *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). Dr. Kohane declares in statement number 4, Charles B. Berde, Gary Strichartz and Robert S. Langer are the co-inventors on the '020 patent and in statement number 5, Berde and Strichartz are not inventors of the claimed invention of the '032 application. Therefore, as evidenced by Dr. Kohane's declaration not all inventors are the same, a different inventive entity. As stated by the House and Senate reports on the bills enacting section 35 U.S.C. 102(e) as part of the 1952 Patent Act, this subsection of 102 codifies the Milburn rule of *Milburn v. Davis-Bournonville*,

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270 U.S. 390 (1926). The Milburn rule authorized the use of a U.S. patent containing a disclosure of the invention as a reference against a later filed application as of the U.S. patent filing date. The existence of an earlier filed U.S. application containing the subject matter claimed in the application being examined indicates that applicant was not the first inventor. Therefore, a U.S. patent, a U.S. patent application publication or international application publication, by a different inventive entity, whether or not the application shares some inventors in common with the patent, is *prima facie* evidence that the invention was made "by another" as set forth in 35 U.S.C. 102(e).

The claims remain rejected.

New Rejection Necessitated by Amendment filed April 14, 2008

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44-51 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Kohane et al. (US 6,326,020).

Kohane et al. disclose combinations of naturally occurring site 1 sodium channel blockers, such as tetrodotoxin (TTX), saxitoxin (STX), decarbamoyl saxitoxin, and neosaxitoxin, with other agents, have been developed to give long duration block with improved features, including safety and specificity (col. 2, lines 30-35). Kohane et al. disclose that in one embodiment, duration of block is greatly prolonged by combining a toxin with a local anesthetic, vasoconstrictor, glucocorticoid (col. 2, lines 36-38). Kohane et al. further disclose the effectiveness of these compositions is enhanced by microencapsulation within polymeric carriers, preferably biodegradable synthetic polymeric carriers. Kohane et al. disclose that providing these formulations as microparticulate compositions yields even longer lasting local anesthesia than that obtained with toxin or local anesthesia in solution (col. 2, lines 47-54). Kohane et al. disclose the combination of TTX-dexamethasone-bupivacaine in microspheres (at least one, two or three in microspheres, instant invention) produces even longer block (5 to 20 days), which will be useful for chronic pain and cancer pain (col. 2, lines 46-49). Kohane et al. disclose local anesthetic is preferably delivered to the patient incorporated into a polymer in the form of microparticles, most preferably microspheres (col. 2, lines 65-67).

Kohane et al. further disclose other forms of the polymers include microcapsules, microencapsulated microspheres, slabs, beads, and pellets, which in some cases can also be formulated into a paste or suspension (pellets, instant invention). Kohane et al. disclose the microspheres have a diameter of between approximately 10 and 200 microns, more preferably between 20 and 120 microns (col. 9, lines 60-62) (diameter

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less than 1 mm, 500 microns, 250 microns and 100 microns, instant invention). Kohane et al. disclose in example 9, the effect of the addition of dexamethasone to TTX and Bupivacaine containing microspheres (col. 22, lines 10-25).

Claims 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Kohane et al. (US 6,326,020) in view of ten Cate (US 6,352,683).

Applicant's Invention

Applicant claims a pharmaceutical composition for suppressing electrical activity in an electrically excitable tissue comprising a site 1 sodium channel blocker, a local anesthetic and a glucocorticoid receptor agonist that is provided in a microparticle. Applicant further claims the composition comprises a targeting agent and that the microparticles are triggered to release the agent.

Determination of the scope of the content of the prior art

(MPEP 2141.01)

The teachings of Kohane et al. are incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Kohane et al. do not teach the addition of a targeting agent of claim 52 or that the microparticle is triggered to release by radio-frequency, beams or any of the other methods stated in claim 54. It is for this reason ten Cate is joined.

ten Cate teaches a local and site-specific drug delivery system for delivering a drug to a specific site (col. 2, lines 42-43). ten Cate teaches the drug delivery system is characterized by the combination of a) a carrier material which reflects, absorbs, or emits electromagnetic or mechanical vibrations enabling the monitoring of the material, b) a drug associated with the carrier material and c) local-delivery means for delivering the carrier material and the drug to the specific site (col. 2, lines 44-50) ten Cate teaches the drug delivery system may also include means for inducing release of the drug from the carrier material when the carrier material is at the specific site, such as means for generating electromagnetic or mechanical vibrations(col. 2, lines 55-59) (triggers, magnetism, instant invention).

ten Cate teaches the carrier material may comprise an ultrasonic contrast agent in the form of microparticles, microbubbles, microspheres, or microcapsules (col. 2, lines 60-62). ten Cate teaches the local-delivery means may comprise a targeting agent associated with the carrier material. ten Cate further teaches the targeting agent is capable of binding to the specific site within the individual (col. 2, lines 65-67-col. 3, line 1). ten Cate teaches the targeting agent may be a protein or an antibody (col. 3, lines 1-5) (antibodies, proteins, instant invention). ten Cate teaches the drug used in the composition may include dexamethasone (col. 3, lines 11-20).

ten Cate teaches the local and site specific drug delivery system is intended to be a system which is capable of transferring or carrying a drug to a specific area or site, at which the system releases the drug in an active or controlled manner enabling the

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interaction of the drug with the specific area or site, prior to or after administration of the drug delivery system to the human (col. 4, lines 60-67).

Finding a prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Kohane et al. and ten Cate and use a targeting agent in the composition. As taught by Kohane et al., the combination of tetrodotoxin, bupivacaine and dexamethasone in microspheres produces a longer block than the combination without microspheres (5 to 20 days), which is useful for chronic pain and cancer pain. One skilled in the art would have been motivated to add the targeting agent to provide drug delivery to specific areas or sites that need treatment, as ten Cate teaches targeting agents do. Given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary, there would have been a reasonable expectation of success in combining the teachings of the cited references to provide a micoparticle composition that targets the specific area or site that needs treatment and that provides longer blockade of the pain.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/Mina Haghighatian/

Primary Examiner, Art Unit 1616